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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/091,605	06/16/1998	TRACY L. BORTS	X-9872	5126

7590 12/17/2003  
ELI LILLY AND COMPANY  
LILLY CORPORATE CENTER  
DROP CODE 1104  
INDIANAPOLIS, IN 46285

EXAMINER

SHUKLA, RAM R

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 12/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/091,605

Applicant(s)

BORTS ET AL.

Examiner

Ram R. Shukla

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 35-60 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 35-60 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 June 1998 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

1. The response filed 9-22-2003 has been received and entered.
2. Claims 35-60 are under consideration.

***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 46-48, 56-58 and 59 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for reasons of record set forth in the previous office action of 4-21-2003.

***Response to Arguments***

Applicant's arguments filed 9-22-2003 have been fully considered but they are not persuasive. Applicants have argued that the references cited in the enablement rejection indicate that in vivo gene therapy is possible and was known in the art. While this fact is not contested that in vivo gene therapy is possible and was known at the time of the invention, it is maintained that the method of in vivo gene therapy was not routine at the time of the invention or even today as discussed in the previous office action. Applicants did not provide any evidence that the claimed invention was enabled. With regard to claim 59, applicants argued:

" The Examiner has not presented any evidence to suggest that inducing insulin secretion in a mammal does not have utility".

It is not clear as to where did the office action suggest that the claimed invention lacked utility. The rejection was enablement under 112 first paragraph

and so were the claims analyzed. Therefore, applicants are moot regarding this point. Again applicant's arguments regarding clinical trials, MPEP and case law citations are misplaced because the office action did not demand results of human clinical trials. Applicants' attention is drawn to page 3 of the office action, which provides the evidence from the art of record regarding the state of the art of gene therapy. Applicants failed to address the issues raised in the previous office action and did not present any evidence as to what undue experimentation will not be required, particularly in view of the cited arts showing the unpredictable state of the art of gene therapy.

Regarding the issue of biological material deposit, applicants arguments that they need not be deposited is not persuasive because claims recite specific vectors/plasmids with a certain name and what is exactly present in the plasmids or vectors or what is the sequence of the plasmids/vectors in not taught in the specification. In other words, while an artisan could not make the particularly named plasmid unless the sequence of the plasmid was known. Therefore, the enablement rejection is maintained for reasons of record set forth in the previous office action of 421-2003.

5. Claims 35-58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for reasons of record set forth in the previous office action of 4-21-2003.

Claim 35 remains rejected because the metes and bounds of the term "mammalian origin" are not clearly described in the specification. Applicants simply argue that the term takes on its plain ordinary meaning, however, applicants did not provide any evidence as to what was its meaning.

It is noted that replacing the term "a stable cell line of mammalian origin" with the term "a stable mammalian cell line" will be remedial.

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 35-44, 49-55 and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Selden et al (US 6,048,724, 4-11-00, effective filing date 11-5-1991) in view of Pakzaban et al (Neuroscience 65:983-996, 1995) for reasons of record set forth in the previous office action of 4-21-2003.

8. Claims 45 is rejected under 35 U.S.C. 103(a) as being unpatentable over Selden et al (US 6,048,724, 4-11-00, effective filing date 11-5-1991) and Pakazaban et al (Neuroscience 65:983-996, 1995) as applied to claims 35-44 and 49-55 above, and further in view of Gromada et al (FEBS LETTERS 1995, 373:182-186) for reasons of record set forth in the previous office action of 4-21-2003.

***Response to Arguments***

Applicant's arguments filed 9-22-2003 have been fully considered but they are not persuasive. Applicants argument that the prior art must contain a

suggestion or motivation to combine the prior art references in such a way as to achieve the claimed invention are misplaced since there is no such requirement and the motivation to combine references may be present in the commonly available knowledge (see MPEP 2144). The art taught that masking of donor cells resulted in enhanced survival of xenotransplants, which is the motivation to immunologically mask cells that are for transplantation. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Next, applicants' arguments that:

"it is inconsistent for the Examiner to argue that the references render the invention obvious while at the same time express doubt at the Applicants' to show the usefulness of the claimed invention"

are misplaced and irrelevant that claims that have been rejected as obvious have not been rejected for enablement and there is no utility rejection.

9. No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory

period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ram R. Shukla whose telephone number is (703) 305-1677. The examiner can normally be reached on Monday through Friday from 7:30 am to 4:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051. The fax phone number for TC 1600 is (703) 703-872-9306. Any inquiry of a general nature, formal matters or relating to the status of this application or proceeding should be directed to the William Phillips whose telephone number is (703) 305-3413.


Please note that effective January 13, the offices for Examiner Shukla, SPE Reynolds and LIE William Phillips will move to the new USPTO location in Alexandria, VA and their phone numbers will change. The new phone numbers will be as follows:

Ram Shukla: **(571) 272-0735**

Deborah Reynolds: **(571) 272-0734**

William Phillips: **(571) 272-0548**

Ram R. Shukla, Ph.D.  
Primary Examiner  
Art Unit 1632

  
**RAM R. SHUKLA, PH.D.**  
**PRIMARY EXAMINER**